K023050

FEB 1 4 2003

Attachment 15
510(k) Summary Statement for the
Reliant BTL 5000 Puls Electrical Stimulation, BTL 5000 Sono Ultrasound, & BTL 5000 Combi Combination Electrical Stimulation & Ultrasound Systems

I. General Information

Submitter:	Reliant Technologies, Inc. 260 Sheridan Avenue Suite 208 Palo Alto, CA 94306
Contact Person:	Anne C Worden Principal Regulatory Consultant AL Voss Associates P.O. Box 405 Angels Camp, CA 95221
Summary Preparation Date:	September 11, 2002

II. Names

Device Names:	Reliant BTL 5000 Puls Electrical Stimulation System Reliant BTL 5000 Sono Ultrasound System Reliant BTL 5000 Combi Combination Electrical Stimulation & Ultrasound System
Primary Classification Name:	Ultrasound and Muscle Stimulator (and Accessories)

III. Predicate Devices

- Chattanooga Group, Inc. Vectra 2C and Vectra 4C (K982317);
- Chattanooga Group, Inc. Vectra Pro 2 and Vectra Pro 4 (K982324);
- Dynatronics Corporation Dynatron 150 Plus Ultrasound (K935728);
- Excel Tech XL Tek Ultra VM Ultrasound (K001166); and
- Empi 300 PV Complete Electrotherapy System (K021100).

IV. Product Description

Reliant BTL 5000 Puls Electrical Stimulation System, BTL 5000 Sono Ultrasound System, and BTL 5000 Combi Combination Electrical Stimulation & Ultrasound systems are comprised of the following main components:

- A system console (including software and control electronics);
- A control and display panel;
- Delivery device accessories (patient cables and electrodes and/or ultrasound cables and sound heads.

V. Indications for Use

The Reliant BTL 5000 Puls Electrical Stimulation System, BTL 5000 Sono Ultrasound System, and BTL 5000 Combi Combination Electrical Stimulation & Ultrasound systems (and the delivery accessories that are used with them) are indicated for use in the stimulating, relaxing, and/or repeatedly contracting muscles by passing electrical currents through electrodes contacting the affected body area in the medical specialties of physical medicine, general and plastic surgery and neurology and/or for use in applying therapeutic deep heat for selected medical conditions such as relief of pain, muscle spasms, and joint contractures in the medical specialty of physical medicine. The Reliant BTL 5000 Puls Electrical Stimulation System, BTL 5000 Sono Ultrasound System, and BTL 5000 Combi Combination Electrical Stimulation & Ultrasound systems are indicated for the treatment and relaxation of muscle spasms, prevention or retardation of disuse atrophy, increasing local blood circulation, muscle re-education, maintaining or increasing range of motion, immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, symptomatic relief of chronic, intractable pain, management of pain associated with post-traumatic or post-operative conditions using electrical stimulation and are indicated for the application of therapeutic deep heat for the treatment of selected medical conditions such as relief of pain, muscle spasms and joint contractures, relief of pain, muscle spasms and joint contractures that may be associated with adhesive capsulitis, bursitis with slight calcification, myositis, soft tissue injuries, shortened tendons due to past injuries and scar tissues, relief of chronic and subchronic pain and joint contractures resulting from capsular tightness and capsular scarring using ultrasound. The combination ultrasound and electrotherapy modes deliver deep heat for pain management (ultrasound therapy) at the same time that electrical stimulation for either pain management or muscle stimulation is being delivered. Only one electrotherapy mode (TENS, High Voltage, Interferential or Premodulated) can be utilized at a time in conjunction with the ultrasound mode.

VI. Rationale for Substantial Equivalence

The Reliant BTL 5000 Puls Electrical Stimulation System, BTL 5000 Sono Ultrasound System, and BTL 5000 Combi Combination Electrical Stimulation & Ultrasound systems share the same general indications for use in physical medicine, general and plastic surgery and neurology applications and share the same or similar basic characteristics and features and, therefore, are substantially equivalent to the Chattanooga Group, Inc. Vectra 2C and Vectra 4C (K982317), the Chattanooga Group, Inc. Vectra Pro 2 and Vectra Pro 4 (K982324), the Dynatronics Corporation Dynatron 150 Plus Ultrasound (K935728) , the Excel Tech XL Tek Ultra VM Ultrasound (K001166), and the Empi 300 PV Complete Electrotherapy (K021100) systems.

VII. Safety and Effectiveness Information

Validation documentation and a comparison of the technical characteristics and features were provided to demonstrate that the Reliant BTL 5000 Puls Electrical Stimulation System, BTL 5000 Sono Ultrasound System, and BTL 5000 Combi Combination Electrical Stimulation & Ultrasound systems are safe and effective, when indicated in specific applications in the medical specialties of physical medicine, general and plastic surgery and neurology.

VIII. Conclusion

The Reliant BTL 5000 Puls Electrical Stimulation System, BTL 5000 Sono Ultrasound System, and BTL 5000 Combi Combination Electrical Stimulation & Ultrasound systems were found to be substantially equivalent to the predicate Chattanooga Group, Inc. Vectra 2C and Vectra 4C (K982317), the Chattanooga Group, Inc. Vectra Pro 2 and Vectra Pro 4 (K982324), the Dynatronics Corporation Dynatron 150 Plus Ultrasound (K935728), the Excel Tech XL Tek Ultra VM Ultrasound (K001166), and the Empi 300 PV Complete Electrotherapy (K021100) systems. The Reliant BTL 5000 Puls Electrical Stimulation System, BTL 5000 Sono Ultrasound System, and BTL 5000 Combi Combination Electrical Stimulation & Ultrasound systems share similar indications for use and characteristics and functional features, and thus are substantially equivalent to, the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 4 2003

Reliant Technologies, Inc.
C/O: Ms. Anne Worden
AL Voss Associates
P.O. Box 405
Angels Camp, CA 95221

Re: K023050
Dated: January 3, 2003
Received: January 6, 2003

Trade/Device Name: BTL 5000 Combi Electrical Stimulation & Ultrasound System with rubber electrodes and sponge covers
Regulation Numbers: 21 CFR 890.5860, 21 CFR 882.5890, 21 CFR 882.1320
Regulation Names: Ultrasound and muscle simulator, transcutaneous electrical nerve stimulator for pain relief, cutaneous electrodes
Regulatory Class: Class II
Product Codes: IMG, GZJ, GXY, LIH

Trade/Device Name: BTL 5000 Puls Electrical Stimulation System with rubber electrodes and sponge covers
Regulation Numbers: 21 CFR 890.5850, 21 CFR 882.5890, 21 CFR 882.1320
Regulation Names: Powered muscle stimulator, transcutaneous electrical nerve stimulator for pain relief, cutaneous electrodes
Regulatory Class: Class II
Product Codes: IPF, GZJ, GXY, LIH

Trade/Device Name: BTL 5000 Sono Ultrasound System
Regulation Number: 21 CFR 890.5300
Regulation Name: Ultrasound diathermy
Regulatory Class: Class II
Product Code: IMI

Dear Ms. Worden:

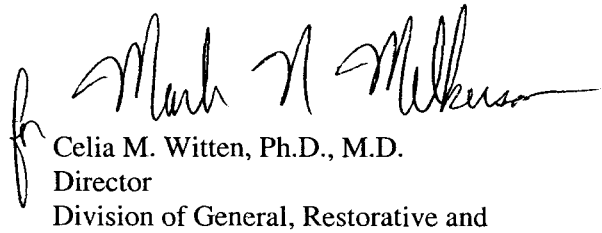
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Attachment 2
Indications For Use Statement as Requested by FDA

510(k) Number (if Known): K023050

Device Name: Reliant BTL 5000 Puls Electrical Stimulation System, BTL 5000 Sono Ultrasound System, and BTL 5000 Combi Combination Electrical Stimulation & Ultrasound System

Indications For Use:

The Reliant BTL 5000 Puls Electrical Stimulation System and the BTL 5000 Combi Combination Electrical Stimulation & Ultrasound System (and the delivery accessories that are used with them) are indicated for use in the medical specialties of physical medicine, general and plastic surgery and neurology for medical purposes/applications requiring:

Electrical Stimulation for Muscle & Soft Tissue Stimulation/Pain Management:

TENS, Russian, High Voltage Therapy Modes

- Treatment and relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle re-education
- Maintaining or increasing range of motion
- Immediate postoperative/post-surgical stimulation of calf muscles to prevent venous thrombosis

TENS, Microcurrent, Interferential and Premodulated Modes

- Symptomatic relief of chronic and/or intractable pain
- Management of acute pain associated with post-traumatic or post-operative conditions

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

510(k) Number K023050

(Optional Format 1-2-96)

Attachment 2
Indications For Use Statement as Requested by FDA

510(k) Number (if Known): K023050

Device Name: Reliant BTL 5000 Puls Electrical Stimulation System, BTL 5000 Sono Ultrasound System, and BTL 5000 Combi Combination Electrical Stimulation & Ultrasound System

Indications For Use:

Continued from Previous Page (page 2 of 2)

The Reliant BTL 5000 Sono Ultrasound System and the BTL 5000 Combi Combination Electrical Stimulation & Ultrasound System (and the delivery accessories that are used with them) are indicated for use in the medical specialty of physical medicine for medical purposes/applications requiring:

Ultrasound for Deep Heat/Pain Management:

- Application of therapeutic deep heat for the treatment of selected chronic and subchronic medical conditions such as:
  - Relief of pain, muscle spasms and joint contractures
  - Relief of pain, muscle spasms and joint contractures that may be associated with:
    - Adhesive capsulitis
    - Bursitis with slight calcification
    - Myositis
    - Soft tissue injuries
    - Shortened tendons due to past injuries and scar tissues
  - Relief of chronic and subchronic pain and joint contractures resulting from:
    - Capsular tightness
    - Capsular scarring

The combination ultrasound and electrotherapy modes deliver deep heat for pain management (ultrasound therapy) at the same time that electrical stimulation for either pain management or muscle stimulation is being delivered. Only one electrotherapy mode (TENS, High Voltage, Interferential or Premodulated) can be utilized at a time in conjunction with the ultrasound mode.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)